



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0378]

Compliance Policy Guide Sec. 690.800 Salmonella in Food for Animals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of guidance for our staff entitled “Compliance Policy Guide Sec. 690.800 Salmonella in Food for Animals” (the CPG). The CPG provides guidance to FDA staff on Salmonella-contaminated food for animals.

DATES: Submit either electronic or written comments on the CPG at any time.

ADDRESSES: Submit written requests for single copies of the CPG to the Food and Feed Policy Staff, Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the CPG.

Submit electronic comments on the CPG to <http://www.regulations.gov>. Submit written comments on the CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance document entitled “Compliance Policy Guide Sec. 690.800 Salmonella in Food for Animals” (the CPG). The CPG provides guidance to FDA staff on Salmonella-contaminated food for animals. The CPG is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The CPG represents FDA’s current thinking on Salmonella-contaminated food for animals. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

In the Federal Register of August 2, 2010 (75 FR 45130), we announced the availability of a draft CPG entitled "Compliance Policy Guide Sec. 690.800 Salmonella in Animal Feed," and gave interested persons an opportunity to submit comments by November 1, 2010, for us to consider before beginning our work on the final version of the CPG. In the Federal Register of October 29, 2010 (75 FR 66769), we published a notice extending the comment period until December 31, 2010. We received numerous comments on the draft CPG and have modified the final CPG where appropriate. The CPG announced in this notice finalizes the draft CPG announced on August 2, 2010.

Changes to the CPG include:

- The title of the CPG is changed from “Salmonella in Animal Feed” to “Salmonella in Food for Animals.” FDA made this change to clarify that the CPG covers all animal food. The term “food for animals” here includes pet food and animal feed.
- The term “Direct Human Contact Animal Feed” has been removed from the CPG, because commenters found the term to be confusing. The term pet food is now used instead. It is defined to mean food for pets and includes treats and chews for pets.

The CPG explains criteria that FDA personnel should consider in recommending enforcement action against food for animals that is adulterated due to the presence of Salmonella. In particular, the CPG provides regulatory action guidance relating to pet food or pet food ingredients that are contaminated with Salmonella. In addition, the CPG provides regulatory action guidance relating to animal feed and animal feed ingredients that are contaminated with certain Salmonella serotypes that are pathogenic to the particular species of animal for which the animal feed or animal feed ingredients are intended. The CPG also contains information that may be useful to regulated industry and the public.

This notice is related to two notices published elsewhere in this issue of the Federal Register, in which FDA is announcing: (1) The removal of 21 CFR 500.35 “Animal feeds contaminated with Salmonella microorganisms,” and (2) the withdrawal of “Compliance Policy Guide Sec. 690.700 Salmonella Contamination of Dry Dog Food.” The enforcement policy in the CPG supersedes the policies articulated in 21 CFR 500.35 and CPG Sec. 690.700.

II. Comments

Interested persons may submit either electronic comments regarding the CPG to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see

ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the CPG at either http://www.fda.gov/ora/compliance_ref/cpg/default.htm or at <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the CPG.

Dated: July 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.